UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

FERNDALE LABORATORIES, INC., a Michigan corporation,

Plaintiff,

Case No. 05-70476

v.

HONORABLE DENISE PAGE HOOD

VERACITY PHARMACEUTICALS, INC., a Florida corporation; BOCA PHARMACAL, INC., a Florida corporation,

Defendants.
_____/

MEMORANDUM OPINION & ORDER DENYING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

Plaintiff Ferndale Laboratories, Inc. brings a false advertising claim pursuant to the Lanham Act, 15 U.S.C. §1051, et seq. Plaintiff also alleges violations under the Michigan Consumer Protection Act, MCL § 440.903, et seq., and claims unfair competition. Among other requests for relief, Plaintiff primarily seeks to enjoin Defendants Veracity Pharmaceuticals, Inc. and Boca Pharmacal, Inc. from directly or indirectly "advertising, promoting, marketing, distributing, selling, representing, or implying . . . that their HC Pramoxine Topcial Cream is the generic drug product, generic name for, substitutable or in any way equivalent to Ferndale's Pramosone products, including Pramosone 2.5% Cream." (Pl.'s Mot. for Prelim. Inj. at 2.)

This matter is before the Court on Plaintiff's Motion for Preliminary Injunction, pursuant to

Fed. R. Civ. P. 65 and Local Rule 65.1, filed on February 7, 2005.[1] Defendants filed a Response, to which Plaintiff replied. For the reasons set forth below, the Court denies Plaintiff's Motion for Preliminary Injunction.

II. STATEMENT OF FACTS

A. Facts as Alleged by Plaintiff

Plaintiff is a "privately owned Detroit-based pharmaceutical company with over 250 employees." (Pl.'s Br. in Supp. at 2.) Plaintiff "manufactures, sells and distributes pharmaceutical products primarily used in dermatology and gastroenterology." (Id.)

> In the late 1970's, Ferndale obtained approval of several Abbreviated New Drug Applications ("ANDA") from the Food and Drug Administration ("FDA"), which granted Ferndale authorization to market a number of prescription drug products containing the two active ingredients, pramoxine hydrochloride and hydrocortisone acetate, for the relief of inflammatory and pruitic manifestations of corticosteroid responsive dermatoses.
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> * * *
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> Ferndale manufactures markets and sells numerous prescription products related to these ANDAs, including Pramosone 1%, which contains 1% pramoxine hydrochloride and 1% hydrocortisone acetate, and Pramosone 2.5%, which contains 1% pramoxine HCl and 2.5% HC. Pramosone comes in several dosage forms, including creams, lotions and ointments. Hydrocortisone acetate is a low-potency topical steroid and Pramoxine HCl a topical anesthetic such that Pramosone provides dual-action relief of inflammation and itch associated with dermatoses.
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> The Pramosone product at issue here is Pramosone 2.5% Cream. Ferndale sells Pramosone 2.5% Cream primarily to major drug wholesalers who in turn sell the product largely to retail pharmacies throughout the United States where the patient goes with a prescription from the doctor to obtain the drug. Ferndale also provides

[1] This Court has already heard, and denied, a similar preliminary injunction motion in Ferndale Pharmaceuticals, Inc. v. Veracity Pharmaceuticals, Inc. and Boca Pharmacal, Case No. 04-72900. The parties have stipulated that the two cases be consolidated for discovery purposes. The 2004 case involves the same basic allegations, but relates to a different drug. The docket sheet for Case No. 04-72900 indicates that Case No. 05-70476 is administratively closed.

> educational support services to physicians to educate them on the benefits of Pramosone 2.5% Cream.
>
> Ferndale has invested substantial time and money in the marketing, promotion, research and development of its hydrocortisone acetate and pramoxine hydrochloride products, including Pramosone 2.5% Cream. The Pramosone products are extremely important to Ferndale's overall business. Pramosone 2.5% Cream alone accounts for over 4% of Ferndale's total gross sales.
>
> Defendants' are piggy-backing off of Ferndale's significant efforts through false statements that are designed to lure doctors, wholesalers, pharmacists and patients into believing that Defendants' product is generically/therapeutically equivalent to Pramosone 2.5% Cream.

(Id. at 3-4) (internal citations omitted).

Defendant, Boca Pharmacal, "develops and markets niche-type generic pharmaceuticals." (Id. at 4.) Defendant, Veracity Pharmaceutical "distributes the Topical Cream product." (Id.) Plaintiff asserts Defendants are falsely promoting their Topical Cream "as a generic drug product equivalent to Pramosone 2.5% cream and represent that Pramosone 2.5% Cream is its 'brand name equivalent.'" (Id.)

> Defendants provide that information orally as well as on the NWDA Standard Product Information Sheets that pharmaceutical companies give to drug wholesalers to induce them to buy and distribute their products. Defendants also distributed a letter to their customers expressly representing that their product is the generic 'equivalent to Ferndale Labs Pramosone.'

(Id.)

Plaintiff also points to the alleged presence of the chemical benzophenone in Defendants' product. Plaintiff alleges its products do not contain this chemical, and maintain that this is yet another discrepancy between the two products further demonstrating the need for a preliminary injunction. At this time, it appears the FDA has yet to take action on any of these allegations.

Finally, Plaintiff points to testing conducted on a batch of Defendants' product allegedly

showing a hydrocortisone stability problem. (Id. at 6.) Plaintiff states none of its batches of Pramosone product suffer from a similar deficiency. Plaintiff argues this allegation provides the Court with yet another reason for granting a preliminary injunction in this instance.

B. Facts as Alleged by Defendants

In Response, Defendants allege Plaintiff "has marketed Pramosone for several decades, does not hold any U.S. patents for its formulation, and has never applied to FDA for approval to market Pramosone." (Defs.' Br. in Opp. at 2) (internal citation omitted). Due to Plaintiff's alleged failure to submit its drugs to FDA for approval, "FDA has never determined whether Veracity's product is generically equivalent to Pramosone." (Id.)

Defendants also point to the following "numerous steps to assure that its product can be properly substituted by pharmacists for Pramosone": (1) both Pramosone and Defendants' product are white creams; (2) both contain 2.5% hydrocortisone acetate and 1% pramoxine HCl as active ingredients; (3) both contain the same excipient base ingredients; (4) "Veracity's product was developed for the relief of inflammation and itching, on an 'as needed' basis, just like Pramosone"; (5) "Veracity audited its third party contract manufacturer to assure total compliance with GMPs (good manufacturing practices) and other applicable FDA regulations"; and (6) "Veracity commissioned an independent laboratory to compare Pramosone and Veracity's product, and that laboratory found the products to be comparable in terms of active ingredients, physical characteristics, and product and package workmanship." (Id. at 3-4) (internal citations omitted).

Concerning the alleged presence of benzophenone in their product, Defendants state Plaintiff has "fail[ed] to mention that FDA has already investigated this issue – at Ferndale's specific request – and declined to take any action against Veracity." (Id. at 5) (internal citation omitted). With

respect to Plaintiff's allegation of a hydrocortisone stability problem existing in Defendants' product, Defendants respond that such an allegation is speculative at best. (Id. at 6.)

III. STANDARD OF REVIEW

A. Preliminary Injunction Standard

Whether a preliminary injunction should issue lies within the sound discretion of the district court. *Golden v. Kelsey-Hayes,* 73 F.3d 648, 653 (6th Cir. 1996). In determining whether to grant or deny an injunction, the district court is required to consider four factors: (1) whether the movant is likely to prevail on the merits; (2) whether the movant would suffer irreparable injury if the court does not grant a preliminary injunction; (3) whether a preliminary injunction would cause substantial harm to others; and, (4) whether a preliminary injunction would be in the public interest. *Connection Distributing Co. v. Reno,* 154 F.3d 281, 288 (6th Cir. 1998) "None of these factors, standing alone, is a prerequisite to relief; rather the court should balance them." *Kelsey-Hayes,* 73 F.3d at 653. A district court is required to make specific findings concerning each of the factors unless fewer are dispositive of the issue. *Performance Unlimited v. Questar Publishers, Inc.* 52 F.3d 1373, 1381 (6th Cir. 1995)

Since Plaintiff's claim is brought under the Lanham Act, this Court must analyze the merits of the request for injunctive relief in the context of that statute.

B. The Lanham Act

The Lanham Act imposes liability on "[a]ny person who . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15

U.S.C. § 1125(a)(1)(B).

The Lanham Act imposes five requirements upon Plaintiff to show a violation based on false advertising under the Lanham Act. Plaintiff must show that: (1) Defendants have made false or misleading statements of fact concerning their own product or another's; (2) Defendants' statement actually or tends to deceive a substantial portion of the intended audience; (3) Defendants' statement is material in that it will likely influence the deceived consumer's purchasing decisions; (4) the advertisements were introduced into interstate commerce; and (5) there is some causal link between the challenged statements and the harm to Plaintiff. *American Council of Certified Podiatric Physicians & Surgeons v. American Bd. of Podiatric Surgery, Inc.*, 185 F.3d 606, 613 (6th Cir. 1999). If Plaintiff can show Defendants made literally false statements, the second requirement noted above will be excused. "[W]here statements are literally false, a violation may be established without evidence that the statements actually misled consumers. Actual deception is presumed." *Id.* at 614.

Applying the facts of this case to the applicable law, this Court finds that Plaintiff has not made a sufficient showing that the balance of the four requisite preliminary injunction factors favors Defendants.

IV. APPLICABLE LAW AND ANALYSIS

A. Likelihood of Success on the Merits

Plaintiff asserts Defendants' representations regarding their cream are literally false. (Pl.'s Br. at 8.) Plaintiff relies on the FDA's standards of bioequivalence to support its contention. Defendants respond by claiming that pharmacists do not consider the FDA standards when evaluating generic equivalence for drugs that have not yet been approved by the FDA. (Defs.' Br.

in Opp. at 6.) While literally false claims lower the bar for success on the merits, claims that are merely ambiguous cannot be deemed literally false. *See IQ Products Co. v. Pennzoil Products Co.*, 305 F.3d 368, 375 (5th Cir. 2002) ("If the statement is shown to be misleading or ambiguous, however, the plaintiff must demonstrate actual deception through direct evidence of consumer reaction to the advertising . . . ."); *see also American Council*, 185 F.3d at 616; *Pizza Hut, Inc. v. Papa John's International, Inc.*, 227 F.3d 489, 497 (5th Cir. 2000); *Johnson & Johnson v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992); *Avila v. Rubin*, 84 F.3d 222, 227 (7th Cir. 1996). Here Defendants' actions when completing the NWDA form are best viewed as ambiguous, since the form asks for a "brand name equivalent," a phrase that is apparently not precisely defined. Plaintiff relies heavily on FDA definitions of "generic equivalence" and "therapeutic equivalence" in claiming that Defendants' statement is literally false. Yet Plaintiff has not provided enough evidence to equate either of the FDA phrases with "brand name equivalence." Barred from proceeding via the literal falsity route, at this time Plaintiff has not demonstrated enough evidence that Defendants' statement actually or tends to deceive a substantial portion of the intended audience to show a likelihood of success on the merits.

Here Plaintiff has not applied for FDA approval of Pramosone, nor does Plaintiff hold any patents concerning the drug. Defendants have created and manufactured a drug that is allegedly chemically equivalent. Defendants also maintain that they have adhered to all manufacturing and applicable FDA regulations in producing their drug. In the absence of any showing of an affirmative duty on the part of Defendants to fulfill any further requirements prior to marketing their product – including conducting clinical trials or medical studies – the Court cannot find that Plaintiff is likely

to succeed on the merits in this action.[2]

B. Irreparable Injury

Generally, the resulting harm from the denial of a preliminary injunction will not be deemed irreparable if it is capable of being redressed by monetary damages. *Overstreet v. Lexington-Fayette Urban County Gov't*, 305 F.3d 566 (6th Cir. 2002); *Basicomputer Corp. v. Scott*, 973 F.2d 507, 511 (6th Cir. 1992). Because Pramosone has been on the market for decades and has a well documented sales history, Defendants argue Veracity's sales will also be easily tracked. (Defs.' Br. in Opp. at 17.) As such, Defendants maintain, Plaintiff's losses can be accurately determined, and are capable of being cured by monetary damages. This is an oversimplified view of Plaintiff's injuries.

As Plaintiff points out, "[i]n cases where false comparative advertising is shown, irreparable injury is presumed." *Abbott Labs. v. Gerber Prods. Co.*, 979 F. Supp. 569, 575 (W.D. Mich. 1997). The reason for this is because false advertising allows "goodwill and reputation [to] be left in the hands of another. This loss of control is an irreparable injury." *Upjohn Co. v. Am. Home Prods. Corp.*, 1996 U.S. Dist. LEXIS 8049 (W.D. Mich 1996). Plaintiff has demonstrated irreparable injury, but this must be balanced against the failure to demonstrate Plaintiff will succeed on the merits.

C. Substantial Harm to Others

Plaintiff does not specifically set forth other parties likely to suffer substantial harm. If Plaintiff were able to show a likelihood of success on the merits, then Plaintiff would likely be able to show that consumers were harmed by the false advertising. This however is not the case.

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[2] The Court must note that the lack of specific regulatory requirements in order to be properly classified a "generic" drug is disconcerting. However, this is a question for Congress and federal agencies such as the FDA.

Plaintiff stands to be harmed by the continued sale of Veracity's cream. Defendants stand to be harmed if sales of its cream are enjoined. Beyond these interested parties however, others are not likely to suffer substantial harm.

D. The Public Interest

Courts have found "a strong public interest in preventing misleading advertisements, particularly with respect to pharmaceutical products." *Genderm Corp. v. Biozone Labs.*, 1992 U.S. Dist. LEXIS 13521, 13555 (N.D. Ill. 1992). However, as Defendants counter, the public interest is served by having low-cost generic drugs available. On par, the public interest, and its safety, are better served by having injunctions issue in cases where pharmaceutical products are sold or distributed with misleading advertisements. This case is not such an instance, as Defendants' statement has not, at this time, been sufficiently shown to be misleading.

IV. CONCLUSION

On the basis of the foregoing, the Court denies Plaintiff's Motion for Preliminary Injunction because Plaintiff has not demonstrated a likelihood of success on the merits at this time. Overall, the balance of equities favors Defendants and denying Plaintiff's Motion.

Accordingly,

IT IS ORDERED that Plaintiff's Motion for Preliminary Injunction **[Docket No. 2, filed February 7, 2005]** is DENIED.

/s/ Denise Page Hood
DENISE PAGE HOOD
UNITED STATES DISTRICT JUDGE

DATED: August 23, 2005